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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,732	04/04/2002	Viktoria Petrovna Yamskova	P67704US0	9698

136 7590 05/27/2005

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EXAMINER	
TELLER, ROY R	

ART UNIT	PAPER NUMBER
1654	

DATE MAILED: 05/27/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/070,732	YAMSKOVA ET AL.	
	Examiner	Art Unit	
	Roy Teller	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *11 March 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7* is/are pending in the application.

4a) Of the above claim(s) *7* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

This office action is in response to the amendment, received 3/11/05, in which applicant amended claims 1-7. Claim 7 is withdrawn as being drawn to non-elected subject matter, see 0704 office action.

Claims 1-6 are pending.

Claim Rejections - 35 USC § 112

Claims 1-6 are/stand rejected under 35 U.S.C. 112, first paragraph for the reasons set forth in the previous office action which are restated below.

Claims 1-6 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for glycoproteins extracted from blood serum, liver, thymus or eye does not reasonably provide enablement for glycoproteins extracted from tissues taken from different organs of human beings and animals. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

In this regard, the application disclosure and claims have been compared per the factors indicated in the decision *In re Wands*, 8 USPQ2d 1400 (Fed. Cir., 1988) as to undue experimentation. The factors include:

1) the nature of the invention;
2) the breadth of the claims;
3) the predictability or unpredictability of the art
4) the amount of direction or guidance presented;
5) the presence or absence of working examples;
6) the quantity of experimentation necessary;
7) the state of the prior art; and,

8) the relative skill of those skilled in the art;

Each factor is addressed below on the basis of comparison of the disclosure, the claims and the state of the prior art in the assessment of undue experimentation.

The claimed invention is drawn to glycoproteins extracted from blood serum, liver, thymus or eye.

The breadth of the claims is excessive with regard to claiming glycoproteins comprising any and all glycoproteins extracted from tissues taken from different organs of human beings and animals. Applicant has only provided guidance for the use of glycoproteins extracted from blood serum, liver, thymus or eye. Applicant have provided no guidance of any other glycoproteins extracted from tissues taken from different organs of human beings and animals. In absence of evidence to the contrary, it would not be expected that any and all glycoproteins extracted from tissues taken from different organs of human beings and animals would act as a medicinal agent . Furthermore, it would not be predictable to the artisan which glycoproteins extracted from tissues taken from different organs of human beings and animals would work in the present invention, nor would it be predictable to the artisan which pathologies could be treated with these glycoproteins.

In consideration of these factors, it is apparent that there is undue experimentation because of a variability in prediction of outcome that is not addressed by the present application. Absent factual data to the contrary, the amount and level of experimentation needed is undue to practice the invention as claimed.

Applicant's arguments were carefully considered but were not found persuasive.

Applicant contends that the present amendments and enclosed experiment results

overcome the rejection. However, the examiner contends that the instant specification only provided guidance for the use of glycoproteins extracted from blood serum, liver, thymus or eye.

Claim Rejections - 35 USC § 102/103

Claims 1-6 are/stand rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as being obvious over Karler et al. (USPN 4,169,139) for the reasons set forth in the previous office action which are restated below.

The claimed invention is drawn to a glycoprotein taken from different organs of human beings and animals, that are soluble in a saturated solution of ammonium sulfate, having an apparent molecular weight of 10-45 kDa and having biological activity in ultra low doses from 10(-12) to 10(-29) mol/liter and lower, and a method of administering such a glycoprotein.

Karler teaches glyco/proteinaceous derivatives – i.e., mucoprotides comprised of proteins and carbohydrates (thus, glycoproteins) which appear to be identical to the presently claimed glycoprotein since they were also obtained from various mammalian organs (such as liver, placenta, spleen, kidney, pancreas, pituitary glands) and also demonstrate biological activity (see, e.g., for example, abstract, column 1-3, and column 11, claim 1). Karler further discloses a parenteral form of the product useful as a treatment (see, e.g., for example, claims 1 and 5, columns 11 and 12) Consequently, the claimed glycoprotein appear to be anticipated by the reference.

In the alternative, even if the claimed glycoprotein is not identical to the referenced glycoproteins (i.e., mucoprotides) with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced glycoprotein (e.g., molecular weights thereof, a method of using the glycoprotein comprising administering the glycoprotein to a subject as a medicinal agent), particularly in view of the similar characteristics which they have been shown to share. Thus, the claimed glycoprotein would have been obvious to those of ordinary skill in the art within the meaning of USC 103. If necessary, the result-effective adjustment in conventional working parameters (e.g., a glycoprotein having biological activity in ultra low doses from 10(-12) to 10(-29) mol/liter and lower, and/or administering a parenteral form thereof)- i.e., the adjustment of particular conventional working conditions is deemed merely a matter of judicious selection and routine optimization which is well within the purview of the skilled artisan.

Accordingly, the claimed invention as a whole was at least *prima facie* obvious, if not anticipated by the reference, especially in the absence of sufficient, clear, and convincing evidence to the contrary.

As discussed in the previous office action, with respect to the above art rejection, please note that the Patent and trademark Office is not equipped to conduct experimentation in order to determine whether the apparent molecular weight range of applicants' glycoproteins differ and, if so, to what extent, from those disclosed by the cited reference. Therefore, with the showing of the reference, the burden of establishing non-obviousness by objective evidence is shifted to the applicants.

Applicant's arguments were carefully considered but were not found persuasive.

Applicant contends that the instant invention is drawn to glycoproteins isolated from an intercellular space of tissues (intracellular matrix) of different organs. The glycoproteins isolated from the intercellular space of tissues is one of the distinctive features of the instant invention, according to applicant. However, the examiner contends that a glycoprotein is claimed, not a method of making a glycoprotein. A glycoprotein obtained by Karler's disclosure or the instant invention's disclosure is still a glycoprotein, as instantly claimed, only the methods of making differ.

In addition, please note that in product –by-process claims, "once a product appearing to be substantially identical is found and a 35 U.S.C. 1-2/103 rejection [is] made, the burden shifts to the applicant to show an unobvious difference." MPEP 2113. This rejection under 35 U.S.C. 102/103 is proper because the "patentability of a product does not depend on its method of production." In re Thorpe, 227 USPQ 964, 966 (Fed. Cir. 1985).

Conclusion

All claims are rejected.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Roy Teller whose telephone number is 571-272-0971. The examiner can normally be reached on Monday-Friday from 5:30 am to 2:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell, can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR

system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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5/23/05

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CHRISTOPHER R. TATE
PRIMARY EXAMINER